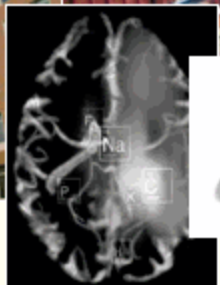
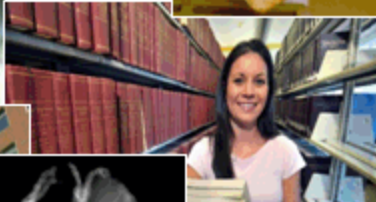
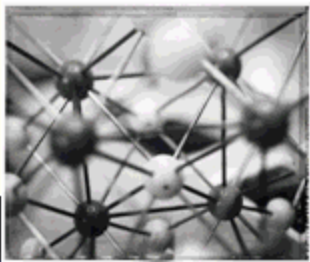


# Office of the Vice Chancellor for Research

## Update on PHS New Rule on Financial Conflicts of Interest (FCOI)

Presentation to Bringing Administrators Together  
April 11, 2012

Jacquelyn Jancius, Director, COI



# **Conflict of Interest – PHS New Rule**

Public Health Services (PHS)  
Regulation, Department of  
Health and Human Services  
42 CFR Part 50 and  
45 CRF Part 94, on Financial  
Conflicts of Interest (FCOI)

Issued on August 25, 2011

Deadline for compliance is August 24, 2012

## **Purpose of Regulation:**

Promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest (FCOI).

# NIH View on FCOI:

“The NIH is committed to preserving the public’s trust that the research supported by us is conducted without bias and with the highest scientific and ethical standards. We believe that strengthening the existing regulations on managing financial conflicts of interest is key to assuring the public that NIH and the institutions we support are taking a rigorous approach to managing the essential relationships between the government, federally-funded research institutions, and the private sector.”

<http://grants.nih.gov/grants/policy/coi/index.htm>

"The public trust in what we do is just essential, and we cannot afford to take any chances with the integrity of the research process."

Dr. Francis Collins

# PHS/HHS Regulation Applies to:

- HHS and PHS:
  - Investigators
  - Sub-recipient Investigators
  - Key research personnel
- Anyone who is responsible for the *design, conduct, or reporting* of HHS and PHS funded research (e.g. consultants)
- May also apply to other sponsored research as required by contract with the sponsor.

## Requirement for Subcontracts :

- Subcontracting institution must have a policy that complies with the new PHS regulation; or
- Subcontracting institution must elect to follow the University's policy and procedures.



# 1995 Reg vs. 2011 Revised Reg:

- Definition of significant financial interest (SFI);
- Extent of Investigator's disclosure of information to Institutions regarding their SFI;
- Institution's management of identified FCOIs;
- Information reported to the PHS funding component (e.g. NIH);
- Information available to the public;
- Investigator training

# What must be disclosed?

All HHS/PHS Investigators and key research personnel must disclose *any* financial interests of the Investigator (and those of the Investigator's spouse or domestic partner, parents, siblings, and children) that:

- reasonably appear to be related to the investigator's institutional responsibilities;
- meet the regulatory thresholds for Significant Financial Interests (SFI)



# Significant Financial Interest (SFI):

- A financial relationship is determined to be a SFI when the value of equity and any remuneration (e.g., salary, royalties, and other payments) received from an external entity at present or in the 12 months *preceding* the disclosure that when aggregated for the individual, one's spouse or domestic partner, parents, siblings, and children total or exceed \$5,000.
- Any equity interest in a non-publicly traded company.
- There is a \$0 de minimis for reporting reimbursed or sponsored travel.

# Overview of SFI

Financial Interest	Examples	Thresholds for SFI
Remuneration, income, salary, and any payment for services	Consulting fees, honoraria, paid authorship	\$5,000 or more
Public equity interest	Stock, stock option, or other ownership interest	Present day market value of \$5,000 or more
Private equity interest	Stock, stock option, or other ownership interest	Any ownership interest regardless of percentage or dollar value.
Intellectual Property (IP) rights and interests	Patents not assigned to the University of Illinois; licenses from the University of Illinois to an external entity; copyrights; royalties that are not paid by the University of Illinois	When profit or remuneration from IP interests meets or exceeds \$5,000; Financial equity interest thresholds apply.
Fiduciary role	Executive role, a voting member of the board	Report fiduciary relationships (even if unpaid) that may be reasonably related to your research or institutional responsibilities; or with an entity the does business with the University.
Sponsored or reimbursed travel	Travel paid by an external entity (including airfare, gas, car rental, hotel room, meals, stipends, etc). Travel must be reported from any entity unless the travel is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined by 20 U.S.C. 1001(a); an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.	\$0 de minimis for reporting; there is no prescribed threshold for qualifying sponsored or reimbursed travel as an SFI. The University must determine when sponsored or reimbursed travel represents a SFI.

# SFI excludes:

- salary, royalties or other remunerations **paid by the University of Illinois**; including intellectual property rights **assigned to the University of Illinois** and agreements to share royalties related to such rights;
- income from investment vehicles (mutual funds or retirement account that are **not managed directly** by the individual);
- income from seminars, lectures, or teaching engagements **sponsored by a federal, state, or local government agency, an Institution of hospital, a medical center, or a research institute thighter education as defined by 20 U.S.C. 1001(a)**; an academic teaching hat is affiliated with an Institution of higher education).;
- income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education as defined by 20 U.S.C. 1001(a).

# Overview of Process at UIC:

- Investigators must disclose external financial relationships *related to the investigator's institutional responsibilities* and those that meet the SFI thresholds (e.g., \$5,000).
- Investigators must disclose all sponsored & reimbursed travel (\$0 de minimus).
- The University must review disclosures and determine which external relationships present a Financial Conflict of Interest (FCOI), implement management mechanisms, and report FCOIs to the PHS agencies.

# What is required of the Investigator?

## Disclosure to the University

Prior to submission, each Investigator must:

- have an up-to-date RNUA disclosure on file and follow the University's *Policy on Conflict of Commitment and Interest*.
- complete the University's Conflict of Interest Certification on the Proposal Approval Form (PAF).
- Complete the **Part I: Investigator Financial Disclosure Form** annually and update within 30 days of acquiring a new SFI.

# What is required of the Investigator?

## Investigator COI Training

Prior to funding, each Investigator must:

- complete an OVCR-approved training session on Conflict of Interest prior to engaging in research related to any PHS/HHS funded grant and at least every 4 years; and immediately under the designated circumstances:
  - University FCOI policies change in a manner that affects Investigator requirements;
  - An Investigator is new to the University;
  - The University finds an Investigator noncompliant with the University's FCOI policy or management plan.

# Investigator COI Training

## Training will cover:

- University's Policy on *Conflict of Commitment and Interest*
- Investigator's responsibilities regarding disclosure of SFI
- The PHS 2011 Regulations on FCOI

## Training options:

- In person trainings
- Online trainings (LMS)

# COI Forms Overview

## **RNUA**

(annual, university-wide for academic staff)

## **COI Certifications (PAF & IRB applications)**

(transactional, specific to research project)

## **Part I: Investigator Financial Disclosure**

(annual for funded PHS researchers; transactional for researcher with other funding)

## **Part II: SEAM**

(annual for funded PHS researchers; transactional for researcher with other funding)



# RNUA (Report of Non-University Activities)

- Annual disclosure of conflict of interest and conflict of commitment
- University academic staff must have prior approval before engaging in external activities
- University academic staff must report their retrospective activities
- Applies to all paid academic staff members, whether part time or full time employees of the university. The academic staff includes academic professionals, postdoctoral associates, and the faculty ranks of professor, associate professor, assistant professor (and all of the foregoing whose appointments contain such terms as "research," "adjunct," "visiting," or "clinical"), instructor, and lecturer. All covered persons are referred to herein as "academic staff members."
- Does **not** apply to civil service staff, students, and medical residents (unless they are also employed as academic staff members).

# COI Certifications

## **Proposal Approval Forms (PAF): COI Certification**

- Transactional disclosure of all Investigators and HHS/PHS key research personnel.
- At submission, all Investigator and HHS/PHS key research personnel must identify any potential financial conflicts of interest related to the research.
- Update with renewal of the grant.

## **IRB Applications (initial, continuing, amendment)**

- Transactional disclosure of all Investigators and key research personnel – regardless of the funding source.
- At submission, all Investigator and key research personnel must identify any potential investigator financial conflicts of interest and institutional conflicts of interest related to the research.
- Update with continuing review and amendments.

# Part I: Investigator Financial Disclosure form

- Annual disclosure of significant financial interests (SFI).
- Must update within 30 days of acquiring a new significant financial interest.
- Covers present day financial interests and financial interests held 12 months *preceding* disclosure.
- Disclosure may be completed prospectively for academic year.
- Applies to all PHS/HHS Investigators, key research personnel, and any person who is *responsible for the design, conduct, and reporting of research*, regardless of percentage of appointment or title. This includes civil service staff, students, and medical residents if they are an investigator or key research personnel.
- Applies to Non-PHS funded researchers that self-identify potential financial interests related to the research.
- Applies to sponsored research when the sponsor requires the University to comply with the PHS regulation.
- Does **not** eliminate the need to complete the RNUA form. All required academic staff must annually complete and update (as needed) their RNUA form.

# Investigators must disclose the following:

- Name of non-University entity
- The financial relationship with the entity:
  - Remuneration includes salary and any payment for services (e.g. consulting fees, honoraria, paid authorship)
  - Equity interest includes stocks, stock options, or other ownership interest (identify if the equity is publicly traded & privately traded)
  - Intellectual property rights (e.g. patents not assigned to the University; licenses from the University of Illinois to the external entity; copyrights; royalties that are not paid by the University.
  - Fiduciary role.
- Reimbursed or sponsored travel

# Investigators must disclose the following:

- Value of the financial interest in dollar ranges:
  - \$0-4,999
  - \$5,000-\$9,999
  - \$10,000-19,999
  - \$20,000-100,000
  - Specific amount if above \$100,000
  - Indicate if value cannot be determined.
- Reimbursed or sponsored travel
  - Purpose of trip(s)
  - Destination(s)
  - Duration (total number of days)
  - Aggregate value of travel expenses

# Financial Conflict of Interest (FCOI)

**Financial Conflict of Interest (FCOI)** exists when the University, through its designated official(s), reasonably determines that the SFI could directly or significantly affect the design, conduct, or reporting of the PHS-funded research.

All determinations of FCOI must be managed through the **Part II: Statement of Explanation and Management (SEAM)** form.

## **Part II: Statement of Explanation and Management (SEAM)**

- Combined with the Part I: Investigator Financial Disclosure Form
- Transactional conflict management plan for any investigator that is determined by the University to have a significant financial that is reasonably related to the research which the University determines to represent a Financial Conflict of Interest (FCOI).
- SEAM must be reviewed annually with renewal for PHS funding.

# SEAM Overview:

- Investigator's role and function in the research
- Justification for conflicted investigator's involvement in the research
- Conflict management mechanisms
- Investigator acknowledgements
- Administrative review and approval



# Forms Summary:

Forms	Who should use this form?	Details
PAF COI Certification	<p>For HHS, PHS research; or as required by the sponsor of the research:</p> <ul style="list-style-type: none"> <li>• Investigators</li> <li>• Key Research Personnel</li> </ul> <p>For industry or other (non-HHS/PHS) sponsored research: Investigators</p>	Link to PAF form
IRB Applications (initial review, continuing review, amendments)	<ul style="list-style-type: none"> <li>• Investigators</li> <li>• Key Research Personnel</li> </ul>	Link to IRB forms
Part I: Investigator Financial Disclosure	<p>For HHS/PHS sponsored research:</p> <ul style="list-style-type: none"> <li>• Investigators</li> <li>• Key Research Personnel</li> </ul> <p>For industry or other (non-HHS/PHS) sponsored research: • Investigators</p>	See FAQs
Part II: Statement of Explanation and Management (SEAM)	<p>On determination of SFI related to a research project:</p> <ul style="list-style-type: none"> <li>• Investigators</li> <li>• Key Research Personnel (for HHS/PHS research)</li> </ul>	<p>The SEAM is required when a significant financial relationship (SFI) reported on Part I: Investigator Financial Disclosure form is reasonably related to a specific research project or an Investigator's institutional responsibilities associated with a specific research project.</p> <p>Relatedness of the SFI may be identified by the Investigator, PI, Unit Executive Officer, COI Office, IRB, or other University Official.</p>

# University Reporting of FCOI:

OVCR will make FCOI report to the funding agency:

- Initial and ongoing (annually, and as needed).
- Report on the management or elimination of FCOIs prior to expenditure of the PHS or HHS funds.
- Report on the management or elimination of FCOIs within 60 days of acquiring or discovering a significant financial relationship.

# Reporting to PHS Awarding Agency:

- **Name** of the entity with which the Investigator has a FCOI
- **Value** of the financial interest
- **Nature of FCOI**, e.g., equity, consulting fees, honoraria
- A description of how the financial interest relates to PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research
- Key elements of the Institution's **management plan**

## Public Accessibility:

The University is required to make information related to the FCOI disclosure and management plans for any PHS/HHS investigator or key research personnel publicly available upon request within 5 business days, whether or not the disclosure resulted in the institution's determination of a FCOI.

## **Monitoring:**

The Unit Executive Officers have an obligation to monitor the disclosure of financial interest and any management plans implemented by the University.

## **Non-compliance:**

The University has the obligation to apply sanctions (including suspending research funding) for an investigator's failure to disclose a financial interest or for an investigator's non-compliance with a management plan.

## **Non-compliance/Mitigation:**

Whenever FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI, failure by the Institution to review or manage an FCOI, or failure to comply with the management plan, the institution shall within 120 days of the determination of non-compliance, complete a retrospective review of the Investigator's activities and the project to determine bias in the design, conduct, or reporting of such research.

## **Deadline to implement:**

Applies to each PHS/HHS grant or cooperative agreement with an issue date of the Notice of Award that is subsequent to the compliance dates of the final rule (including noncompeting continuations) no later than,

**August 24, 2012**

*or* immediately upon the University posting the revised policy on the public website.



# NIH Online Resources:

Department of Health and Human Services 42 CFR Part 50 and 45 CFR Part 94: Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Services Funding is Sought and Responsible Prospective Contractors (August 2011)

2011 FCOI Regulation:

<http://federalregister.gov/a/2011-21633>

NIH FAQs:

[http://grants.nih.gov/grants/policy/coi/coi\\_faqs.htm](http://grants.nih.gov/grants/policy/coi/coi_faqs.htm)

## Contacts:

[www.research.uic.edu/conflict](http://www.research.uic.edu/conflict)

Jacquelyn Jancius, COI Director  
[jancius@uic.edu](mailto:jancius@uic.edu); (312) 996-4070

Korin Hunt, COI Coordinator  
[Kisota2@uic.edu](mailto:Kisota2@uic.edu); (312) 996-3642

[COI@uic.edu](mailto:COI@uic.edu) – Jacquelyn & Korin

# Questions?

